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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,191	12/16/2005	Masayuki Tsuchiya	1254-0300PUS1	3952

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1656	

NOTIFICATION DATE	DELIVERY MODE
11/09/2009	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/561,191	TSUCHIYA ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16,19 and 22-49* is/are pending in the application.

4a) Of the above claim(s) *1-16 and 24-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

This Office Action is in response to the paper filed September 17, 2009.

Claims 1-16 and 24-49 are withdrawn from further consideration because these Claims are drawn to non-elected inventions. Claims 17, 18, 20, and 21 have been canceled. Claims 19, 22, and 23 are under examination.

Withdrawal of Objections and Rejections:

The objection to the disclosure because it contains an embedded hyperlink and/or other form of browser-executable code is withdrawn.

The rejection of Claims 19, 22, and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, ie, new matter, is withdrawn.

Maintenance of Rejections:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 19, 22, and 23 are again rejected under 35 U.S.C. 102(e) as being anticipated by Kanda et al. U.S. 2004/0110282 (filing date April 9, 2003).

Kanda et al. teach a cell in which activity of GDP-fucose protein is decreased. See Abstract. In paragraph [0391] they teach that any host cell can be used in the method of suppression of fucose transporter as long as it has a gene encoding GDP-fucose transporter. In paragraphs [0009-0011] they teach that a Chinese hamster ovary cell (CHO cell) is used (**Claims 19 and 22**).

In paragraphs [0021], [0217] and [0284] they teach that a gene disruption technique that comprises targeting a gene encoding GDP-fucose transporter (**Claim 19**).

In paragraph [0036] they teach that RNA is introduced into the cell by using a vector. In paragraphs [0143] and [0286] they teach a target vector for homologous recombination or an RNA interference (RNAi) that targets GDP-fucose transporter where the gene disruption method may be any method that can disrupt the gene of the target enzyme (**Claim 23**). In paragraphs [0368] and [0376] they teach that the expression vector or vector that is autonomously replicable in the host cell can be integrated into the chromosome, and that it comprises a promoter at such position that the designed RNAi gene can be transferred (**Claim 23**).

While Kanda et al. teach the cDNA encoding the Chinese hamster fucose transporter as SEQ ID NO: 35 – see also Examples 2+ - one skilled in the art would recognize that the CHO comprises the genomic DNA encoding this fucose transporter and that the use of RNAi or gene disruption refers to this gDNA regardless of what the specific nucleic acid sequence is.

Therefore, the claims are anticipated.

Applicants urge that Claim 19 has been amended to recite that the Chinese hamster fucose transporter gene having SEQ ID NO: 1 is disrupted and SEQ ID NO: 1 is not disclosed in Kanda et al. Given that Kanda et al. teach to use Chinese hamster ovary (CHO) cells and teach nucleic acid encoding Chinese hamster fucose transporter as SEQ ID NO: 35, the teachings of Kanda et al. continue to anticipate the Claims because one skilled in the art would recognize that the CHO cell comprises gDNA (which comprises the cDNA in total or in exon fragments) encoding the Chinese hamster fucose transporter. Thus, the nucleic acid sequence of SEQ ID NO: 1 is inherent to Kanda et al.'s teaching to disrupt this gene. See *In re Donahue* (226 USPQ 619) which sets forth that the art applied under 35 USC 102 must only sufficiently describe the claimed invention to be applied as prior art against the invention. *In re Schauman* 197 USPQ 5) the courts defined anticipation as the disclosure in the prior art of a thing substantially identical with the claimed invention. Further, that no more is required of a reference than that it set forth the substance of the invention.

It appears that Applicant and Examiner are arguing past each other. It is the Examiner's position that SEQ ID NO: 1 is inherently in CHO cells. Thus, Claim 19 can be read as an isolated Chinese hamster cell wherein its fucose transporter gene is disrupted. In paragraphs [0021], [0217] and [0284] Kandi et al. teach that a gene disruption technique that comprises targeting a gene encoding GDP-fucose transporter. Kandi et al. is applied to Claim 19 because Kandi et al. must only sufficiently describe the claimed invention to be applied as prior art against the invention, in accordance to In

re Donahue. That is, the teaching of a CHO cell having its GDP fucose transport gene disrupted is the same as the claimed Chinese hamster cell wherein its fucose transporter gene is disrupted. Kandi et al. need only teach what is claimed.

The Examiner may see the issue differently if the gene disruption were based on SEQ ID NO: 1, that is, if Applicants had disrupted SEQ ID NO: 1 at specific nucleotides, for example, and claimed it. This would not be considered to be anticipated or obvious over Kandi et al. because without the sequence in hand Kandi et al. cannot teach or render obvious were in the fucose transport gene to insert disruptive nucleotides.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 19, 22, and 23 are again provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8

of copending Application No. 11793649. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are drawn to cells having the fucose transporter gene suppressed or disrupted.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that Applicants have requested that this rejection be held in abeyance.

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson whose telephone number is 571-272-0946. The examiner can normally be reached on 6:00 AM - 4:00 PM, Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Karen Cochrane Carlson/
Primary Examiner, Art Unit 1656